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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,867	12/06/2001	Audrey Goddard	P3230R1C1	6830

30313 7590 09/13/2004

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EXAMINER	
HELMS, LARRY RONALD	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,867	EATON ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. The request filed on 7/9/04 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/006867 is acceptable and a RCE has been established. Claims 42-51 are pending and are currently under prosecution. An action on the RCE follows.

2. Claims 42-51 have been amended and are pending and under examination.

3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

4. The following Office Action contains NEW GROUNDS of rejections.

5. NOTE: The request to delete inventors is accepted and the inventors have been deleted.

Rejections Withdrawn

6. The rejection of claims 42-51 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

7. The rejection of claims 42-45, 47, 50-51 under 35 U.S.C. 102(b) as being anticipated by Feng et al (WO 99/24836, published 5/99) is withdrawn in view of the new ground of rejection.

8. The rejection of claims 42-51 under 35 U.S.C. 102(b) as being anticipated by Baker et al (WO 99/63088, published 12/99) is withdrawn because the claims are granted the priority date of 8/24/00 and this rejection would be a 102(a) rejection now, however, the filing of the 131 declaration stated that conception of the invention was prior to 12/99 (see page 18 of response filed 7/9/04).

Response to Arguments

9. The rejection of claims 42-51 under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility is maintained.

The response filed 7/9/04 has been carefully considured but is deemed not to be persuasive. The response states that that the application provides data showing that PCR provides utility and gene amplification is an essential mechanism of oncogene activation and mRNA for PRO180 polypeptide is overexpressed in rectal tumors compared to normal and the invention is useful in diagnosing cancer (see page 9 of response) and in the majority of cases gene expression correlates with levels of protein expression as evidenced by the declaration of Dr. Grimaldi (see page 9 of response) and the submitted declaration of Dr. Polakis states that it remains a central dogma that increased levels of mRNA are predictive of increased levels of protein (see page 10 of

response). In response to this argument, the declaration has been carefully considured but is deemed not to be persuasive. The declaration states that we have showed that in 80% of the observations they have found that increased levels of a mRNA correlates with a change in protein levels. In response to this argument, the examiner cited art in the 112 first rejection that supports that mRNA over-expression does not correlate with protein over-expression. While the declaration may show protein over-expression in some cases, the references cited on page 11 of the response, only show mRNA overexpression. Even though the declaration does show some protein correlation, there are equally references that show this not to be the case and these were cited in the rejection such as Chen et al (Molecular and Cellular Proteomics 1:304-313, 2002) underscore the unpredictability in the art as showing that protein expression does not correlate with gene over-expression. Again the response does not address these references. Thus, the references cited by the examiner are examples that the art is unpredictable with regard to protein over-expression and each case must be considered separately and there is no data to indicate that the protein of SEQ ID NO:2 or that which is at least 95% to SEQ ID NO:2 is overexpressed in tumor.

The response further states that the declaration of Dr. Ashkenazi explains that even if one assumes arguendo that it is more likely than not that there is no correlation between gene expression and increased protein expression, the claimed invention would still have utility as evidenced by the declaration (see page 12 of response). The declaration states that if a gene is amplified in tumor

but the corresponding gene product is not over-expressed then the clinician need not treat a patient with agents that target the gene product. In response to this argument, the claims are directed to the polypeptide and therefore utility lies in its utility. It is immaterial whether the clinician would not treat the gene product.

10. The rejection of claims 42-51 under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is maintained for the reasons above.

11. The rejection of claims 42-43, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

The response filed 7/9/04 has been carefully considered but is deemed not to be persuasive. The response states that based on the detailed description of the cloning and expression of variants of PRO180 in the specification, the description of gene amplification assay and description of testing the ability of test variant polypeptides in the assay, one skill in the art would know that applicants possessed the invention as claimed (see page 15 of response). In

response to this only SEQ ID NO:1 is amplified in tumors which encodes SEQ ID NO:2 and there is no polypeptide that is overexpressed in rectal tumors. Describing assays to find the polypeptide does not describe such polypeptides. The specification does not describe any other nucleic acid that encodes any polypeptide that is 95-99% identical to SEQ ID NO:2 which is encoded by a nucleic acid that is over-expressed in rectal tumors.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class.

12. The rejection of claims 42-43, 50-51 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The response filed 7/9/04 has been carefully considered but is deemed not to be persuasive. The response states as pointed out above, applicants have established the utility arguing that more likely than not that since SEQ ID NO:1 is amplified in rectal tumor, the polypeptide of SEQ ID NO:2 is over-expressed in rectal tumors and the specification enables one skill in the art to make and use other polypeptides that are 95 and 99% identical to SEQ ID NO:2 (see page 16 of the response). In response to this argument, the specification does not describe how to make polypeptides that are 95-99% identical to SEQ ID NO:2

wherein the nucleic acid is overexpressed. The specification does not teach a screen or other such molecules. In addition the arguments presented does not overcome the utility rejection. Therefore one would not know how to make or use such molecules.

Priority

13. The examiner acknowledges the priority statement filed 7/9/04 stating that the claimed invention is given the priority date of 8/24/00 (see page 9 and 18 of response.

The following is a NEW GROUND of rejection

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. Claims 42-45, 47, 50-51 are rejected under 35 U.S.C. 102(a) as being anticipated by Feng et al (WO 99/24836, published 5/99).

The claims recite an isolated polypeptide having at least 80% amino acid sequence identity to a polypeptide of SEQ ID NO:2 and fused to an epitope tag.

Feng et al teach a polypeptide that is 100% identical to SEQ ID NO:2. This rejection is being made due to the priority grated and is consistent with the enablement because for a 102 rejection the art must teach how to make.

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)

> Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

> Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999)
> Thus viewed as a whole, the Polla disclosure shows that the natural result flowing from the operation as taught would result in alignment of the laser light over the hair follicle, as claimed. This was true even thought Polla did not mention the goal of hair removal. Therefore, the Court held that the192 patent was invalid as anticipated.

> "Inherency is not necessarily coterminus with the knowledge of those skilled in the art ... Artisans of ordinary skill in the art may not recognize the inherent characteristics of the prior art."

> 190 F.3d at 1347

The response filed 7/9/04 has been carefully considured but is deemed not to be persuasive. The response states that the application claims are granted the priority date of 8/10/98 wherein the entire SEQ ID NO:1 and 2 are disclosed. In

response to this argument, while the sequences may be disclosed the utility of overexpressed in tumor is not. In addition, applicants admit on the record that the claims get the priority of 8/24/00 based on utility disclosed in the PCT US00/23328 application. Therefore, applicants may file a 131 declaration to overcome the reference with a 5/99 date. The declaration filed previously which was effective to overcome the Baker reference is not appropriate because it states that applicant had the invention prior to 12/99 not 5/99. Applicants cite the Stempel Doctrine and cite that the provisional that describes SEQ ID NO:1 and 2 of 8/98 supplies evidence that the claimed invention was disclosed and were in possession prior to 5/99. In response to this argument, the provisional does not indicate that SEQ ID NO:1 is amplified in tumor as claimed.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms

571-272-0832